PATENT ABSTRACTS OF JAPAN

(11)Publication number :

09-140800

(43)Date of publication of application: 03,06,1997

(51)Int.Cl.

A61M 25/00

A61M 39/00

(21)Application number: 07-302981

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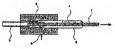
(54) CATHETER TUBE AND ITS PRODUCTION

21,11,1995

(57)Abstract:

(22)Date of filing:

PROBLEM TO BE SOLVED: To prevent the exposure, etc., of knitting and braiding of metallic wires and the dislodgment of a front end tube consisting of a UV curing resin compan, having no knitting and braiding and to improve quality and reliability by connecting a torque transmission part provided with the knitting and braiding of the metallic wires between the inner and outer layers consisting of a UV curing resin compan, and the front end tube on the same axis. SOLUTION: The torque transmission part 6 is constituted by applying the knitting and braiding 4 of the metallic wires on the outer periphery of the inner layer tube consisting of the UV curing resin compan, and forming the outer layer tube 5 consisting of the UV curing resin compan, on its outer periphery. The front end tube 7 is formed of the UV curing resin compsn. to the same diameter as the diameter of the inner layer tube 3 without including the knitting and braiding. The torque transmission part 6 and the front end tube 7 are set in a mold 8 and the UV curing resin compsn. is poured into the mold from a resin injecting part 9 and is cured to connect both 6, 7. For example, a urethane acrylate based UV curing resin compsn., etc., are used as the UV curing resin compsn.



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CLAIMS

[Claim(s)]

[Claim 1]An inside diameter with a torque transmission part provided with a braid which consists of metal wires between a inner layer tube and an outer layer tube which consist of an ultraviolet-curing-resin constituent with the above-mentioned inner layer tube and an equal diameter. And a catheter tube which connects an end tube which consists of an ultraviolet-curing-resin constituent which does not have the above-mentioned braid on the same axle with an ultraviolet-curing-resin constituent, and is characterized by things.

Claim 2]An inside diameter with a torque transmission part provided with a braid which consists of metal wires between a inner layer tube and an outer layer tube which consist of ultraviolet rays and a heat-ouring resin composition with the above—mentioned inner layer tube and an equal diameter. And a catheter tube which connects an end tube which consists of ultraviolet rays and a heat-curing resin composition which do not have the above—mentioned braid on the same axie with an ultraviolet—rusing—resin constituent, and is characterized by things. [Claim 3]The catheter tube according to claim 2, wherein a contrast medium is blended into the above—mentioned ultraviolet rays and a heat-curing resin composition which do not have the above—mentioned ultraviolet rays and a heat-curing resin composition.

[Claim 5]After applying one or more layers of fiquefied ultraviolet-curing-resin constituents on line objects, such as a metal wire, and making this irradiate with and harden ultraviolet-curing-resin constituents on line objects, such as a metal wire, and making this irradiate with and harden ultraviolet rays in a manufacturing method of the catheter tube according to claim 1, give a braid which becomes this periphery from a narrow diameter metal wire, and. After applying a liquefied ultraviolet-curing-resin constituent to the circumference of this braid above further, making this irradiate with and harden ultraviolet rays and forming a torque transmission part, Remove a hardening resin constituent and a braid of a tip part of this torque transmission part, and a line object is exposed. A manufacturing method of a catheter tube characterized by sampling the abovementioned line object after inserting a flexible end tube object which consists of an ultraviolet-curing-resin constituent in this exposed line object and connecting these torque transmission part and an end tube with an ultraviolet-curing-resin constituent and not tube object and connecting these torque transmission part and an end tube with an ultraviolet-curing-resin constituent and red tube with an ultraviolet-curing-resin constituent after that.

[Claim 6]In a manufacturing method of the catheter tube according to claim 2, apply liquefied ultraviolet rays and one or more layers of heat-curing resin compositions on line objects, such as a metal wire, and irradiate this with ultraviolet rays, and. After making it heat and harden, give a braid which becomes this periphery from a narrow diameter metal wire, and. After applying a liquefied ultraviolet-curing-resin constituent to the circumference of this braid above further, making this irradiate with and harden ultraviolet rays and forming a torque transmission part, Remove a resin composition and a braid of a tip part of this torque transmission part, and a line object is exposed, A manufacturing method of a catheter tube characterized by sampling the above-mentioned line object after inserting a flexible end tube which consists of ultraviolet rays and a heat-curing resin composition in this exposed line object and connecting these torque transmission part and an end tube object with an ultraviolet-curing-resin constituent after that. [Claim 7]A manufacturing method of the catheter tube according to claim 6 blending a contrast medium beforehand into the above-mentioned ultraviolet rays and a heat-curing resin

composition.

[Claim 8]A manufacturing method of the catheter tube according to any one of claims 5 to 7 providing a heat-curing silicone layer in the surface of the above-mentioned line object beforehand.

[Claim 9]A manufacturing method of the catheter tube according to any one of claims 5 to 8, wherein sectional shape of the above-mentioned line object is either of the round shape, ellipse form, and glasses types.

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DETAILED DESCRIPTION

[Detailed Description of the Invention]

[0001]

[Field of the Invention]This invention relates to a catheter tube used in medical institutions, such as a hospital, and a manufacturing method for the same.

[0002]

[Description of the Prior Art] In order to pour a drug solution and a contrast medium into a patient's predetermined region in the living body from the exterior in medical institutions, such as a hospital, or to discharge body fluid in the living body etc., the tube shape medical device which has the flexibility called a catheter is used, but, Generally, at the time especially of insertion, the high operativity and safety which can reach to a predetermined part in the living body correctly without damaging an intermediate blood vessel wall, a living body organ, etc. are demanded from this catheter being inserted in the living body using a thin blood vessel, an urethra, etc. [0003] Therefore, this catheter comprises a tip part which was [that it is easy to bend, without damaging a blood vessel and a living body organ 1 rich in elasticity, and a torque transmission part holding the torque convectivity for making this tip part reach certainly to a predetermined part. And after giving with a braider the braid which becomes a periphery of the tube body (inner layer) which consists of a plasticity plastic which inserted the wire first as the conventional manufacturing method, for example from a corrosion-resistant metal wire, Then, the torque transmission part which passed the metallic mold which heated this tube body, made that braid embed in a tube body, and provided the reinforcement layer in that circumference is formed Next, after forming the reinforcement layer located in the tip end part of this torque transmission part, i.e., the tip part which removed metal braids by the electrochemical remove-metals method, and was rich in elasticity. Cut the base catheter which carried out package coating of the outer layer for the plasticity plastic by extrusion as well as the periphery of that tube body, and formed the torque transmission part and the tip part by turns so that it may become the length of the actual catheter which consists of one torque transmission part and tip part, so that this reinforcement layer may be covered, and. The method of forming by drawing out from a tube body is known after extending the above-mentioned wire.

[0004]

[Problem(s) to be Solved by the Invention]By the way, in the conventional catheter manufacturing method which was mentioned above. In order to take the outer diameter small a large inside diameter as much as possible, when thickness of a catheter tube is made thin, there is a problem which the metal braids embedded in the inner layer tube expose to the tube inside, or unevenness produces in a tube inner surface.

[0005]In order obtain uniform torque convectivity and to stick a inner layer and an outer layer, a glue line may be provided between them, but when it does so, there is a problem of thickness becoming thick or a work process increasing.

[0006]As mentioned above, in order to make the tip part into structure without a braid (reinforcement layer), remove the braid of a tip part electrochemically, or have connected another tube body in which the braid is not included with melting connection, adhesives, etc. at the tip of a torque transmission part, but. In order to remove a braid, the device and process for it are needed, manufacturing efficiency is bad and there is inconvenience from which an inside diameter and an outer diameter change in those terminal areas by the method by melt adhesion. By connection by adhesives, it is hard to obtain the stable intensity from adhesion area being small, and the worries about the tip part pasted up during the operation being missing in the living body etc. can be considered. Especially the thing for which it is stabilized and the anxious catneter of such lack which is not is manufactured in connection of different—species plasticity obstacis is very difficult.

[0007]Then, this invention is thought out in order to solve such SUBJECT effectively, and it is a thing.

The purpose does not have fear, such as exposure of the braid in a torque transmission part, exfoliation, omission of an end tube, is quality, and is providing a new super-narrow diameter catheter excellent in reliability, and a manufacturing method for the same.

[8000]

[Means for Solving the Problem]In order to solve an aforementioned problem a catheter tube of this invention. An inside diameter with a torque transmission part provided with a braid which consists of a narrow diameter metal wire between a inner layer tube and an outer layer tube which consist of an ultraviolet-curing-resin constituent or ultraviolet rays, and a thermosetting resin composition with the above-mentioned inner layer tube and an equal diameter. And an end tube which consists of an ultraviolet-curing-resin constituent or ultraviolet rays, and a heatcuring resin composition which do not have the above-mentioned braid, A manufacturing method for coming to connect with an ultraviolet-curing-resin constituent on the same axle, and obtaining such a catheter tube and, Apply further liquefied ultraviolet rays and a thermosetting resin composition, or an ultraviolet-curing-resin constituent above on line objects, such as a metal wire, UV irradiation or after making it heat and harden, give this a braid which becomes this periphery from a narrow diameter metal wire, and. After carrying out spreading hardening of the ultraviolet-curing-resin constituent liquefied around this braid above further and forming a torque transmission part. Remove a hardening resin constituent and a braid of a tip part of this torque transmission part, and a line object is exposed, After inserting a flexible end tube object which consists of ultraviolet rays and a thermosetting resin composition, or an ultravioletcuring-resin constituent in this exposed line object and connecting these torque transmission part and an end tube object with an ultraviolet-curing-resin constituent after that, The abovementioned line object is sampled.

[0009]Since this invention formed a torque transmission part from a liquefied ultraviolet—uningresin constituent or ultraviolet rays, and a heat—uning resin composition as mentioned above, and ultraviolet rays or heat is used together and it was made to stiffen this, in order that material may go into a braid eye easily. Exfoliation with a inner layer tube in a braid eye and an outer layer tube stops arising. Therefore, inconvenience, such as exposure of a braid by embedding a braid in a inner layer tube and exfoliation at the time of providing a glue line, is lost like before, and thinning can also be attained easily.

[0010]Remove a hardening resin constituent and a braid of a tip part of a torque transmission part, and a line object is exposed, A flexible end tube which consists of ultraviolet rays and a thermosettling resin composition, or an ultraviolet-curing-resin constituent is inserted in this exposed line object. Then, since the above-mentioned line object was sampled after connecting these torque transmission part and an end tube with an ultraviolet-curing-resin constituent, it is good, without an inside diameter of a terminal area of an end tube and a torque transmission part changing, or heights coopuring, and firm connection is attained.

[001] As shown in Claim 3 or 7, by putting a contrast medium in this resin composition, in the time of actual use, recognition of a catheter by X-rays etc. becomes easy, and operativity improves. The resin composition used in this case needs to use a resin composition hardened not only with UV irradiation but with heat. That is, it is because it is necessary to use heat together with ultraviolet rays in order to perform sufficient hardening from hardening only by ultraviolet rays becoming insufficient, if a contrast medium is added in a resin composition. [0012] If a heat-curing silicone layer is beforehand provided in the surface of a line object and a

heat-curing silicone layer is beforshand formed in an inner surface of the above-mentioned inner layer tube and an end tube as shown in Claim 4 or 8, activity grant of a tube inner surface will be attained, and the drawing-out nature of a line object improves greatly.

[0013]Since this invention applied a liquefied resin composition on a line object, as shown in Claim 9, it can obtain a catheter tube of desired shape easily by using sectional shape of a line object as a round shape, an ellipse form, a glasses form, etc.

[0014]

[Embodiment of the Invention] Next, an embodiment of the invention is described. [0015] The ultraviolet-curing-resin constituent used for this invention consists of photopolymerization nature oligomer, a photopolymerization nature monomer, a photopolymerization initiator, etc. fundamentally. With among these, photopolymerization nature oligomer (prepolymer). For example, an epoxy acrylate system, an epoxidized oil acrylate system, a urethane acrylate system, A polyester urethane acrylate system, a polyether urethane acrylate system, A polyester-acrylates system, a polyether acrylate system, a vinyl acrylate system. A silicone acrylate system, a polybutadiene acrylate system, a polystyrene ethyl methacrylate system, It is various oligomer, such as a polycarbonate dicarbo NETO system, an unsaturation polyester system, polyene / thiol system, and has the functional group which has an unsaturated double bond, for example, an acrylyl group, a methacryloyl group, an allyl group, and two or more vinyl groups. Fluoride substitution could be carried out and this photopolymerization nature oligomer may combine two or more sorts of cage NOGOMA. With a photopolymerization nature monomer, one piece or the publicly known compound which it has two or more pieces can be used for functional groups, such as an acrylyl group, a methacryloyl group, a vinyl group, and an allyl group, into a molecule. A photopolymerization initiator has the work which makes the polymerization reaction of photopolymerization nature oligomer or a monomer start, and has a role which receives ultraviolet rays and generates a free radical. For ultraviolet-rays bridge construction, this free radical is required, and a photoinitiator is a substance which will absorb a specified wavelength by UV irradiation, will be in an electric excitation state, and is easy to generate a radical. For example, there are a benzoin ether system, a ketal system, an acetophenone series, a benzophenone series, a thioxan ton system, etc., and various photopolymerization initiators can be used according to the purpose. [0016]On the other hand, a thermal polymerization start catalyst is further added to the

ultraviolet-rouring-resin constituent which turns into ultraviolet rays and a heat-ouring resin constituent which turns into ultraviolet rays and a heat-ouring resin composition from the above-mentioned photopolymerization nature oligomer, a photopolymerization initiator, sto. And what is necessary is for heat to decompose easily, to generate a free radical as this thermal polymerization start catalyst, and just to perform a hardening reaction. For example, the ketone peroxides which are organic peroxide, peroxy ketals, hydroperoxide, dialkyl peroxide, dialoy peroxide, are oxyl esters as pecies, par oxyl catronate, and peroxy mono-carbonate are mentioned. There are radical polymerization initiators, such as an azo compound, etc.

[0017]In this invention, using a liquefied ultraviolet-curing-resin constituent or ultraviolet rays, and a heat-curing resin composition, As mentioned above, by supposing that it is liquefied, the thinning of a tube is easy and it is because material goes into a braid eye easily and it is not necessary to embed a braid in a inner layer tube, or to provide a glue line.

[0018]It can protect by compensating the fall of the hardenability due to the fall of an ultraviolet—rays penetration with a contrast medium at the hardening reaction by heat in addition. As this contrast medium, although barium sulfate, bismuth oxide, tungsten carbide, etc. are mentioned, in particular by this invention, it is not limited to these.

[0019]Although it does not limit in particular for the construction material of the line object used for this invention, what consists of corrosion-resistant metal, such as SUS, is preferred. [0020]Heat-curing silicone is provided in a line body surface after the coating by the resin composition mentioned above in order to improve drawing-out nature of a line object. Activity grant becomes easy by providing a silicone layer in a tube inner surface. Although it does not limit in particular for this heat-curing silicone, the thing excellent in detachability and surface activity with a line object is good desirably. And when the line object excellent in such

detachability and surface activity is used, formation of a heat-curing silicone layer may be omitted. [0021]

[Example] Next, concrete working example of this invention is described. [0022](Working example 1) As shown in drawing 2 (B), on the annealed copper wire (line object) 1 with an outer diameter of 2.0 mm, carry out covering hardening of the heat-curing silicone (SR2410: made by Dow Corning Toray Silicone) at 5**1 micrometer in thickness, form the heatcuring silicone layer 2, and on it. After applying a liquefied urethane acrylate system ultravioletcuring-resin constituent (shore hardness D80), it was made to harden through a UV irradiation furnace, and the 20**2-micrometer-thick inner layer tube 3 was formed. Next. it is a braid (the element wire diameter of 0.035 mm) to the periphery of this inner layer tube 3 by a braider, Give SUS3044 and a liquefied urethane acrylate system ultraviolet-curing-resin constituent (shore hardness D80) is further applied to the periphery of this braid 4, After having stiffened this through the UV irradiation furnace, forming the outer layer tube 5 and forming the torque transmission part 6 with an outer diameter of 2.2 mm, this was cut to 2.5 m, covering of the piece terminal was removed 5 mm, and the annealed copper wire 1 was exposed. Next, as shown in drawing 2 (A), using the metal wire 1 with an outer diameter of 2.0 mm, covering hardening of the urethane acrylate system ultraviolet-curing-resin constituent (shore hardness D70) was carried out at the same process, covered wire with an outer diameter [without a braid] of 2.15 mm was produced, and the 0.1-m end tube 7 which extracted the metal wire 1 was produced. Next, this end tube 7 is inserted in the portion which the annealed copper wire 1 of the torque transmission part 6 exposed 4 mm. Set to the mold 8 as shown in drawing 1, and a urethane acrylate system ultraviolet-curing-resin constituent (shore hardness D80) is poured in from the resin injection part 9 formed in the mold 8, After making this irradiate with and harden ultraviolet rays and connecting both, the metal wire 1 of the torque transmission part 6 was drawn out, and the catheter tube was obtained.

[0023]And as a result of investigating exfoliation by four copies of braids of the torque transmission part 6 by twisting and crookedness, exfoliation of the inner layer tube 3 and the outer layer tube 5 did not produce at all five catheter tubes produced in this way, but both were joined in one. Even if it performed 50 crookedness of a tip terminal area of 40R, lack of the end tube 7, a crack, etc. were hardly generated. There is no influence by the braid 4 also about appearance, and what has a smooth and flat-tapped inner surface was obtained. [0024](Working example 2) As shown in drawing 3 (B), on the annealed copper wire (line object) 1 with an outer diameter of 2.0 mm, carried out covering hardening of the heat-curing silicone (SR2410: made by Dow Corning Toray Silicone) at 5**1 micrometer in thickness, and formed the heat-curing silicone layer 2, and also. After applying the liquefied urethane acrylate system ultraviolet curing and heat-curing resin composition (shore hardness D80) which 25 % of the weight of bismuth oxide of the contrast medium added. After stiffening this through a UV irradiation furnace and a heating furnace and obtaining the 20**2-micrometer-thick inner layer tube 3a. It is a braid (the element wire diameter of 0.035 mm) to the periphery of the inner layer tube 3a by a braider. Give SUS3044 and a liquefied urethane acrylate system ultraviolet-curingresin constituent (with the shore hardness D80 and no contrast medium) is further applied to the periphery, After stiffening this through the UV irradiation furnace similarly and forming the outer layer tube 5a with an outer diameter of 2.2 mm, this was cut to 2.5 m and the torque transmission part 6a which removed covering of the piece terminal 5 mm was produced. Next, as shown in drawing 3 (A), the metal wire 1 with an outer diameter of 2.0 mm is used, Covering hardening of the urethane acrylate system ultraviolet-curing-resin constituent (shore hardness D70) which 25 % of the weight of bismuth oxide of the contrast medium added at the same process was carried out, covered wire with an outer diameter [without a braid] of 2.15 mm was produced, and the 0.1-m end tube 7a which extracted the metal wire 1 was produced. And this end tube 7a is inserted in the exposed portion of the annealed copper wire 1 of the torque transmission part 6a 4 mm. It set to the mold shown in drawing 1, and the urethane acrylate system ultraviolet-curing-resin constituent (with the shore hardness D80 and no contrast medium) was poured in, after irradiating with and stiffening ultraviolet rays, the metal wire 1 of

the torque transmission part 6a was removed, and the catheter tube was obtained. [0025] And when exfoliation was investigated by twisting and crookedness, exfoliation did not produce at all five catheter tubes which were carried out in this way and produced like working example 1, and lack, a crack, etc. were not generated in 50 crookedness of a tip terminal area of 40R. There is no influence by a braid also about appearance, and the smooth surface thing was obtained

[0026](Comparative example 1) After extruding thermoplastic polyurethane (PERESEN 2363–55D: Dow Chemical Japan, Inc.) 30**5 micrometers in thickness and covering it on annealed copper wire with an outer diameter of 2.0 mm, The braid (the olement wire diameter of 0.035 mm, SUS304) was given to the periphery with the braider, thermoplastic polyurethane was further covered on the periphery, and it was considered as the outer diameter of 2.2 mm. This was cut to 2.5 m, the metal wire was extracted, and the torque transmission part was produced. Next, the thing without the metal braids which extruded and covered thermoplastic polyurethane to annealed copper wire with an outer diameter of 2.0 mm, and were made into the outer diameter of 2.2 mm was produced, and the 0.1-m end tube which extracted the metal wire was produced. This was connected to one end of a previous torque transmission part by thermal melting arrival, and the catheter tube was obtaired.

[0027] And when exfoliation in the braided layer part of a torque transmission part was investigated for five produced catheter tubes by twisting and crookedness, whenever it repeated twisting and crookedness, exfoliation advanced. In 50 crookedness of a tip terminal area of 40R, although lack was not produced, it is easy to produce a crack. Unevenness of the braid arose in the appearance with a braid part of the torque transmission part.

(1028) (Comparative example 2) After extruding thermoplastic polyurethane 30**5 micrometers in thickness and covering it on outer diameter the annealed copper wire of 2.0 mm, give a braid (the element wire diameter to 10.035 mm, SUS304) with a braider to a periphery, and it lets the metallic mold dice which heated this pass, After making a braid eat into a inner layer, thermoplastic polyurethane was further extruded and covered on the periphery, and it was considered as the outer diameter of 2.2 mm. This was cut to 2.5 m, the metal wire was extracted, and the torque transmission part was produced. Next, the thing without the metal braids which extruded and covered thermoplastic polyurethane to annealed copper wire with an outer diameter of 2.0 mm, and were made into the outer diameter of 2.2 mm was produced. The thing without the metal wire was produced. This was connected to one end of a previous torque transmission part by thermal melting arrival, and the catheter tube was obtained.

[0029]Although it was not about one comparative example, when exfoliation in the braided layer part of a torque transmission part was investigated for five produced catheter tubes by twisting and crookedness, and twisting and crookedness were repeated, exfoliation occurred. In 50 crookedness of a tip terminal area of 40R, although lack was not produced, it is easy to produce a orack. Since the braid was made to eat into a inner layer, the braid was selectively exposed in the tube and the crack arose in the exposed part by crookedness.

[0030](Comparative example 3) After extruding the thermoplastic polyurethane (PERESEN 2363-55): Dow Chemical Japan, Inc.) which 25 % of the weight of bismuth oxide of the contrast medium added 30**5 micrometers in thickness and covering it on annealed copper wire with an outer diameter of 2.0 mm, The braid (the element wire diameter of 0.035 mm, SUS304) was given to the periphery with the braider, thermoplastic polyurethane was further covered on the periphery, and it was considered as the outer diameter of 2.2 mm. This was out to 2.5 m, the metal wire was extracted, and the torque transmission part was produced. Next, the thing without the metal braids which extruded and covered the thermoplastic polyurethane which 25 % of the weight of bismuth oxide of the contrast medium added to annealed copper wire with an outer diameter of 2.0 mm, and were made into the outer diameter of 2.2 mm was produced, and the 0.1-m end tube which extracted the metal wire was produced. This was connected to one end of a previous torque transmission part by thermal melting arrival, and the catheter tube was obtained.

[0031] And when exfoliation in the braided laver part of a torque transmission part was

investigated for five produced catheter tubes by twisting and crookedness, whenever it repeated twisting and crookedness, exfoliation advanced. In 50 crookedness of a tip terminal area of 40R, although lack was not produced, it is easy to produce a crack. Unevenness of the braid arose in the appearance with a braid part of the torque transmission part.

[0032](Comparative example 4) After extruding the thermoplastic polyurethane which 25 % of the weight of bismuth oxide of the contrast medium added 30**5 micrometers in thickness and covering it on outer diameter the annealed copper wire 6 2.0 mm, After having given the braid (the element wire diameter of 0.035 mm, SUS304) with the braider to the periphery, letting the metallic mold dice which heated this pass and making a braid eat into a inner layer, thermoplastic polyurethane (with no contrast medium) was further extruded and covered on the periphery, and it was considered as the outer diameter of 2.2 mm. This was cut to 2.5 m, the metal wire was extracted, and the torque transmission part was produced. Next, the thing without the metal braids which extruded and covered thermoplastic polyurethane to annealed copper wire with an outer diameter of 2.0 mm, and were made into the outer diameter of 2.2 mm was produced, and the 0.1-m and tube which extracted the metal wire was produced. This was connected to one end of a previous torque transmission part by thermal melting arrival, and the catheter tube was obtained.

[0033]And although it was not about one comparative example, when exfoliation in the braided layer part of a torque transmission part was investigated for five produced catheter tubes by twisting and crookedness, and twisting and crookedness were repeated, exfoliation occurred. In 50 crookedness of a tip terminal area of 40R, although lack was not produced, it is easy to produce a crack. Since the braid was made to eat into a inner layer, the braid was selectively exposed in the tube and the crack arose in the exposed part by crookedness.

[Effect of the Invention]In short, it used having used liquefied ultraviolet rays or a heat-curing resin composition by this invention above.

That from which exfoliation does not produce not making a braid embed like before at a glue line or a inner layer by that cause, either in a braided layer is obtained easily.

From having connected the end tube and the torque transmission part using a metal wire, ultraviolet curing resin, and a mold, it is firm and good connection without inside diameter change or heights is made. Therefore, the outstanding effect that anxious quality super-marrow diameter catheter tubes which are not, such as exfoliation by a torque transmission part, exposure of a braid, and omission of an end tube, can be obtained by being stabilized etc. can be demonstrated.

[Translation done.]

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DESCRIPTION OF DRAWINGS

[Brief Description of the Drawings]

Drawing 1 It is an explanatory view showing one gestalt of the manufacturing method of this

[Drawing 2](A) is a cross-sectional view showing one gestalt of the end tube of a catheter tube.
(B) is a cross-sectional view showing one gestalt of the torque transmission part of a catheter tube.

[<u>Drawing 3]</u>(A) is a cross-sectional view showing other gestalten of the end tube of a catheter tube. (B) is a cross-sectional view showing other gestalten of the torque transmission part of a catheter tube.

[Description of Notations]

1 Line object

2 Heat-curing silicone layer Three (3a) Inner layer tube

4 Braid

5 (5a) outer layer tubes

Six (6a) Torque transmission part

7 (7a) end tubes

bloM 8

9 Resin injection part

[Translation done.]

(19)日本国特許庁 (JP)

四公開特許公報(A)

(II)特許出願公開番号 特開平9-140800

(43)公開日 平成9年(1997)6月3日

(51) Int.Cl.*	微別紀号	庁内整理番号	FΙ			技術表示箇所
A61M 25/00	306		A61M	25/00	306B	
39/00					320B	

審査請求 未請求 請求項の数9 OL (全 6 頁)

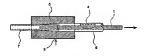
(21) 出願番号	物顧平7~302981	(71)出淵人	000005120	
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(54) 【発明の名称】 カテーテルチュープ及びその製造方法

(57)【要約】

【課題】 本発明の課題はトルク伝達部での編組の輸出 や製態、及び先端チューブの脱落等の責がなく高品質で 信頼性に優れた新規な超細をカテーテル及びその製造方 法を提供するものである。

「解決手段」 上記機器を解決するために本発時は、第 外級原性化断に対象からなら作用をラニーブ3と分解 ープラとの間に相径金属線からなる環想4を備えたトル ク伝達館6と、内性が上の水浦チューブ3と同様で、か レ上記機44を有しない未外線を使き組入物からなる 先端チューブ7とを、紫外線変化級修能点物で同種上に 複数する。



【特許請求の範囲】

【結束章』】 紫外線派に総監組成物からなる内閣テュ 一プと外閣チュープとの間に金配線からなる線組を備え たトルク伝道部と、内径が上流り勝チューブと四様で、 かつ上空編組を看しない紫外線硬化総価温域物からなる ためまりまってどと、紫外線変化総価温域物からなる 接近でなることを特徴とするカテーテルチューブ。

[請求罪②] 禁外極及び軽極化相談指求機物からなる内 磨チュープと外層シュープとの間に金融がからな延期 を備えたトルク伝達部と、内弦が上記内解チュープと同 径で、かつ上記解形を有しない電外的なり発症化機能到 成物からなる先端チュープとを、繁別な変化制能到。 で同種上に接続してなることを特徴とするカテーテルチューブ。

【請求項3】 上記紫外線及び蒸凝化樹脂組成物中に造 影剤が配合されていることを特徴とする請求項2記載の カテーテルチューブ。

[請求項4] 上記内層チューブ及び先端チューブの内面に、熱硬化シリコーン層が形成されていることを特徴とする請求項1又は2記載のカテーテルチューブ。

【請求項7】 上記紫外線及び熱硬化樹脂組成物中に予め造影剤を配合したことを特徴とする請求項6記載のカテーテルチューブの製造方法。

(請求項8] 上記線状体の表面に予め熱硬化シリコーン機を倒せるようたしたとと参考とするまであってのいずれかに記載のカテーテルチューブの製造方法。 (請求項9] 上記線状体の所面形状が実用形、棉写 形、機能形のいずれかであること特徴とする請求項5 ~8のいずれかに記載のカテーテルチューブの製造方 法。

【発明の詳細な説明】

[0001]

「発明の属する技術分野」本発明は病院などの医療機関 で用いられているカテーテルチューブ及びその製造方法 に関するものである。 (0002)

(従来の技術] 病院等の医療機関においては患者の生体 内の所途離位が外部から顕確や造態別を生えしたり、生 供内の保障で養殖情であため、カテーカルと素がされる可 規作を育するチューブ状の散療器長が用いられている が、一般に、このカテーカルは細・血管や原理等を利用 して生物は作用を尤有えるようとっていることから、特 20 に構入時において、途中の血管壁や生体器宣等を傷つけ ることなく正確に生体内の所定の順所まで問題できるよ うな高い機能や定金件が要求されている。

[0003] そのため、このカテーテルは、血管、生体 器官を傷つけずに曲げやすく弾力性に富んだ先端部と、 この先端部を所定の箇所まで残実に到達させるためのト ルク伝達性を保持したトルク伝達部とから構成されてい る。そして、その従来の製造方法としては、例えば、先 ず丸線を挿入した可塑性プラスチックからなるチューブ 休 (内層) の外周に耐食性の金属線からなる編組を編組 機で施した後、引き続き、このチューブ体を加熱した金 型に通過させてその縲組をチューブ体内に埋め込ませて その周囲に補強層を設けたトルク伝達部を形成する。次 に、このトルク伝達部の先端部分に位置する補強層、す なわち金属缰組を電気化学的金属除去法により除去して 弾力性に富んだ先端部を形成した後、この補強層を覆う ようにそのチューブ体の外周に同じく可塑性プラスチッ クを押出しにより外層を一括被覆してトルク伝達部と先 端部とを交互に形成したベースカテーテルを一つのトル ク伝達部と先端部とからなる実際のカテーテルの長さと なるように切断すると共に、上記丸線を延伸後、チュー プ体から引き抜くことにより形成する方法が知られてい

rnnn43

る。

【発明が解決しようとする課題】ところで、上述したような従来のカテーテル製造方法では、その外径を膨かさく、かつ内をたとさく吸るためた、カケーテループの厚さを誇くしたりすると、内層チューブに埋め込まれた金原編組がチューブ内限に断さしてきたり、チューブ内面に四点が生にたりする態度がある。

50 [0005] また、均一なトルク伝達性を得るべく内層

と外層とを密着させるには、その間に接着層を設ける場合があるが、そうすると、内厚が厚くなったり、加工工程が増えてしまうなどの問題がある。

[0007] そこで、本別用はこのような課題を有効に 解決するために実出されたものであり、その目的はトル ク伝達者での課題の提出や実際、及び先輩チュープの配 20 落等の点がなく高品質で信頼性に優れた新規な起酬をカ テーテル及びその製造方法を提供するものである。 [0008]

【課題を解決するための手段】上記課題を解決するため に本発明のカテーテルチューブは、紫外線硬化樹脂組成 物又は紫外線及び熱硬化性樹脂組成物からなる内層チュ ープと外層チューブとの間に細径金属線からなる細組を 備えたトルク伝達部と、内径が上記内層チューブと同径 で、かつ上記編組を有しない紫外線硬化樹脂組成物また は紫外線及び勢硬化樹脂組成物からなる先端チューブと 30 を、紫外線硬化樹脂組成物で同軸上に接続してなるもの であり、また、このようなカテーテルチューブを得るた めの製造方法は、金属線等の線状体上に液状の紫外線及 び勢硬化性権脳組成物又は紫外線硬化機脂組成物を一層 以上途布し、これに紫外線照射または加熱して硬化させ た後、この外周に縄径金属線からなる編組を施すと共 に、この編組の周囲に液状の紫外線硬化樹脂組成物を--層以上塗布硬化させてトルク伝達部を形成した後、この トルク伝達部の先端部の硬化樹脂組成物及び編組を除去 して線状体を露出させ、この露出した線状体に紫外線及 40 び熱硬化性機能組成物又は紫外線硬化構能組成物からな る可撓性の先端チューブ体を嵌め込み、その後、これら トルク伝達部と先端チューブ体とを紫外線硬化樹脂組成 物で接続した後、上記線状体を抜き取るようにしたもの である。

[0 0 0 9] 本界明社上述したように、トルク伝達解を 球状の無外端壁に能断振物欠生態機能機 切 サード系、ポリスチレンエチルメタクリレート系、ボ 単成物から形成し、これを崇外線があるいは熱を併用して 悪化できるようにしたことから、縁起目に材料が入りや 本報目での対解すープと外房チューブ 50 延、メタクリロイル系、フリル系 ビンルを全を個以上

との剥離が生じなくなる。従って、従来のように、内暦 チューブに編組を埋め込むことによる編組の露出や、接 着層を設けた際の剥離等の不部合が無くなり、また、薄 肉化も容易に達成できる。

【0010】また、トルク伝達部の先端部の硬化樹脂組成物及び類組を除去して線状体を霧出させ、この露出した線状体に紫外線及び縁硬化性樹脂組成物又は紫外線硬化樹脂組成物からなる可接性の先端チューブを接め込み、その後、これらトルケ伝達器と先端チューブとを紫

の 外級硬化協勝組成物で接続した後、上記様状体を接き取るようにしたことから、先端テューブとトルク伝達師との接続館の内径が変化したり、凸部が発生することなく良好で、独固な接続が返えされる。

【0011】また、前米四3分ドにデオタンに、この倒断 耐風散物に定診解を入れることにお、実際の使用 において、X競等によるカテーテルの影響が容易とな り、操作性が向上する。向、この場合、使用する極端目 類物は振労保証がだけでなく、然によっても感代する 耐風減物を用いる必要がある。すなわち、倒燃風水物中 に進影料を振力すると、紫外体のみでの様化が干さ なってためた。元分な便化を行うためには、鍼外棒と共 た数を併用するめ悪効あるかである。

【0012】また、請求項4や8に示すように、総状体の変額に予め熱板性シリコーン層を設け、比配門勝子一プ及行先端テープの内部に予め熱限化シリコーン層を形成するようにしておけば、チューブ内面の括性付与が連成されると共に、線状体の引抜き性が大きく向上する。

【0013】また、さらに、本祭四は流状の機能組成物 を稼状体上に塗布するようにしたことから、前球切ら 示すように、線状体の財雷形状を実円形、相平所、限線 形等にすることにより、所望形状のカテーテルチューブ を容易に得ることができる。 【0014】

【発明の実施の形態】次に、本発明の実施の形態を説明 する

 有するものである。また、この光電合性オリゴマはフッ 霧置換されたものでも良く、2種以上のオリノゴマを担 み合わせても良い。また、光重合性モノマとは、分子中 にアクリロイル基、メタクリロイル基、ビニル基、アリ ル基などの官能基を1個又は2個以上有する公知の化合 物を用いることができる。さらに、光重合開始剤とは、 光重合性オリゴマやモノマの重合反応を開始させる働き を持つもので、紫外線を受けフリーラジカルを生成する 役割を持つ。紫外線架橋のためにはこのフリーラジカル が必要で光開始剤は紫外線照射により特定波長を吸収し て爾気的励起状態となり、ラジカルを発生しやすい物質 である。例えば、ベンゾインエーテル系、ケタール系、 アセトフェノン系、ベンゾフェノン系、チオキサントン 系などがあり、目的に応じて穏々の光重合開始剤を用い ることができる。

【0016】一方、紫外線及び熱硬化樹脂組成物とは、 上記光重合性オリゴマ、光重合性モノマ、光重合開始剤 等からなる紫外線硬化樹脂組成物に、さらに熱重合開始 触媒を添加したものである。そして、この熱重合開始触 媒としては、熱により容易に分解し、フリーラジカルを 20 発生し硬化反応を行うものなどであればよい。例えば、 有機過酸化物であるケトンパーオキサイド類、パーオキ シケタール類、ハイドロパーオキサイド類、ジアルキル パーオキサイド類、ジアシルパーオキサイド類、パーオ キシルエステル猫、パーオキシルカルボネート類、パー オキシモノカーボネート類等が挙げられる。また、アゾ 化合物等のラジカル重合開始剤等がある。

【0017】本発明において、液状の紫外線硬化樹脂組 成物又は紫外線及び熱硬化樹脂組成物を用いるのは、上 述したように、液状とすることにより、チューブの薄肉 30 化が容易でかつ、細組目に材料が入りやすくなって、内 層チューブに編組を埋め込んだり、接着層を設ける必要 がないためである。

【0018】造影剤を添加において紫外線透過の低下に よる硬化性の低下を、熱による硬化反応で補うようにす ることにより防ぐことができる。この造影剤としては、 硫酸パリウム、酸化ビスマス、タングステンカーパイト などが挙げられるが、本発用では特にこれらに限定され るものではない。

【0019】本発明に使用する線状体の材質について は、特に限定するものではないが、SUS等の耐食性の 金属からなるものが好ましい。

【0020】また、線状体表面に熱硬化シリコーンを設 けるのは、上述した樹脂組成物による被覆加工後、線状 体の引抜性を良くするためである。さらに、チューブ内 面にシリコーン層を設けることで、活性付与が容易とな る。尚、この熱硬化シリコーンについては、特に限定す るものではないが、望ましくは、線状体との剥離性や表 面活性に優れたものが良い。そして、このような剥離性 や表面活性に優れた線状体を用いた場合には熱硬化シリ 50 に被状のウレタンアクリレート系紫外線硬化樹脂組成物

コーン艦の形成を省略しても良い。

[0021]

【実施例】次に、本発明の具体的実施例を説明する。 【0022】 (実施例1) 図2 (B) に示すように、外 祥 2. 0 mmの軟銀線(線状体) | 上に熱硬化シリコー ン (SR2410:東レ・ダウコーニング・シリコーン (株) 製) を厚さ5±1μmに被覆硬化して熱硬化シリ コーン層2を形成し、その上に、液状のウレタンアクリ レート系紫外線硬化樹脂組成物(ショア硬度D80)を 塗布した後、紫外線照射炉を通して硬化させ、厚さ20 土2μmの内層チューブ3を形成した。次に、福組機に より、この内層チューブ3の外層に細細(紫線径0.0 35mm、SUS304) 4を施し、さらにこの編組4 の外周に液状のウレタンアクリレート系紫外線硬化樹脂 組成物 (ショア硬度 D80) を塗布し、紫外線照射炉を 通してこれを硬化させて外層チュープ5を形成し、外径 2. 2 mmのトルク伝達部6を形成した後、これを 2. 5 mに切断し、その片端末の被覆を5 mm除去して軟鋼 線1を露出した。次に、図2(A)に示すように、外径 2. 0mmの金属線1を用い、同様な工程でウレタンア クリレート系紫外線硬化樹脂組成物(ショア硬度D7 を被覆硬化させ、細組のない外径2.15mmの被 覆線を作襲し、金属線 | を扱いた 0. 1 mの先端チュー ブ7を作製した。次に、この先端チューブ7をトルク伝 連部6の歌銅線1の露出した部分に4mm挿入し、図1 に示すような型8にセットし、その型8に形成された樹 **脂注入部9からウレタンアクリレート系紫外線硬化接脂** 組成物(ショア硬度D80)を注入し、これに紫外線を 照射して硬化させて両者を接続した後、トルク伝達部 6 の金屋線1を引き抜いてカテーテルチューブを得た。 【0023】そして、このように作製したカテーテルチ

ュープ5本を整回及び屈曲によりトルク伝達総6の縄組 4部での剥離を調べた結果、内層チューブ3と外層チュ ープ5の剥離は全く生じず、両者は一体的に接合されて いた。また、先端接続部の40Rの屈曲50回を行って も、先端チューブ7の欠落及び割れ等は殆ど発生しなか った。さらに、外観についても編組4による影響はな く、内面が平滑で面一なものが得られた。

【0024】 (実施例2) 図3 (B) に示すように、外 40 径2.0mmの軟鋼線(線状体) [トに熱硬化シリコー ン(SR2410: 東レ・ダウコーニング・シリコーン (株) 製) を厚さ5±1 μmに被覆硬化して熱硬化シリ コーン層2を形成した上に、造影剤の酸化ビスマス25 重量%添加した液状のウレタンアクリレート系紫外線硬 化養熱硬化樹脂組成物 (シュア硬度D80) を然在した 後、これを紫外線照射炉及び加熱炉を通して硬化させ、 厚さ20±2μmの内層チューブ3aを得た後、綱組機 によりその内層チュープ3aの外周に編組(素線径0. 035mm、SUS304) 4を施し、さらにその外周

(5)

(ショア硬度D80、浩影削無し)を塗布し、これを同 様に紫外線照射炉を通して硬化させて外径2.2mmの 外層チューブ5aを形成した後、これを2.5mに切断 し、片端末の被覆を5mm除去したトルク伝達部6aを 作製した。次に、図3 (A) に示すように、外径2. 0 mmの金属線1を用い、同様な工程で造影剤の酸化ビス マス25重量%添加したウレタンアクリレート系紫外線 硬化樹脂組成物 (ショア硬度D70) を被覆硬化させ、 編組のない外径2、15mmの被覆線を作製し、金尾線 1を抜いた O. 1 mの先端チュープ 7 a を作製した。そ して、この先端チューブ7aをトルク伝達部6aの紋្ 線1の露出部分に4mm挿入し、図1に示す型にセット し、ウレタンアクリレート系紫外線硬化樹脂組成物(シ ョア硬度D80、造影剤無し)を注入し、紫外線を照射 して硬化させた後、トルク伝達部6 a の金属線1を除去 してカテーテルチューブを得た。

【0025】そして、このようにして作製したカテーテ ルチューブ 5 本を撚回及び屈曲により剥離を調べたとこ ろ、実施例1と同様に、制離は全く生じなく、また、先 端接続部の40Rの屈曲50回において、欠落及び割れ 20 等は発生しなかった。さらに、外観についても編組によ る影響はなく、平滑な表面なものが得られた。

[0026] (比较例1) 外径2.0mmの軟鋼線上に 熱可塑性ポリウレタン樹脂(ペレセン2363-55 D:ダウ・ケミカル日本(株))を厚さ30±5 μm押 出し被覆した後、縄組掛により外周に縄組(素線径0. 035mm、SUS304)を施し、さらに外周に熱可 塑性ポリウレタン樹脂を被覆し、外径2.2mmとし た。これを2.5mに切断し、金属線を抜いてトルク伝 達部を作剪した。次に外径2.0mmの軟鋼線に勢可塑 30 を駆べたところ、擦向や屈曲を繰り返す毎に到鍵が進行 性ポリウレタン樹脂を押出し被覆し外径2.2mmとし た金属縞組のないものを作製し、金属線を抜いた0、1 mの先端チューブを作製した。これを先のトルク伝達部 の片末端に熱融着により接続し、カテーテルチューブを 得た。

[0027] そして、作製したカテーテルチュープ5本 を拠回及び屈曲によりトルク伝達部の編組層部での剥離 を調べたところ、拠回や屈曲を繰り返す毎に剥離が進行 した。また、先端接続部の40Rの屈曲50回におい て、欠落は生じなかったが、割れが生じやすいものであ 40 った。さらに、縉細部を持つトルク伝達部の外側には鑑 紐の凹凸が生じた。

【0028】(比較例2)外径2.0mm軟鋼線上に熱 可塑性ポリウレタン樹脂を厚さ30±5 um押出し被覆 した後、編組機により外周に編組(素線径0.035m m、SUS304)を施し、これを加熱した金型ダイス を通して、編組を内層に食い込ませた後、さらにその外 周に熱可塑性ポリウレタン樹脂を押出し被覆し、外径 2. 2mmとした。これを2. 5mに切断し、金属線を の軟鋼線に勢可塑性ボリウレタン樹脂を押出し装置し外 径2.2mmとした金属階組のないものを作製し、金属 線を抜いた0.1mの先端チューブを作製した。これを 先のトルク伝達部の片末端に熱胞着により接続し、カテ ーテルチューブを得た。

【0029】作製したカテーテルチューブ5本を撚回及 び屋曲によりトルク伝達部の縄組層部での剥離を調べた ところ、比較例1ほどではないが然回や屈曲を繰り返す と剥離が発生した。また、先端接続部の40Rの屈曲5 0回において、欠落は生じなかったが、割れが生じやす いものであった。さらに、編組を内層に食い込ませたた め、部分的にチュープ内に細組が鑑出し、屈曲により、 総出部に割れが生じた。

[0030] (比較例3) 外径2. 0 mmの軟鋼線上 に、造影剤の酸化ピスマス25重量%添加した熱可塑性 ポリウレタン極階(ペレセン2363-55D:ダウ・ ケミカル日本 (株)) を厚さ30±5μm押出し被覆し た後、編組概により外間に綱組(素線径0.035m m、SUS304) を施し、さらに外間に熱可塑性ポリ ウレタン樹脂を被覆し、外径2、2mmとした。これを 2. 5 mに切断し、金属線を抜いてトルク伝達部を作製 した。次に、外径2.0mmの軟鋼線に造影剤の酸化ビ スマス25重量%添加した熱可塑性ポリウレタン樹脂を 押出し被覆し外径2、2mmとした金属緩緩のないもの を作製し、金属線を抜いた0.1mの先端チューブを作 製した。これを先のトルク伝達部の片末端に熱融糖によ り接続し、カテーテルチューブを得た。

【0031】そして、作製したカテーテルチュープ5本 を撚回及び屈曲によりトルク伝達部の編組層部での剥離 した。また、先端接続部の40Rの屈曲50回におい て、欠落は生じなかったが、割れが生じやすいものであ った。さらに、縄組部を持つトルク伝道部の外観には復 組の凹凸が生じた。

【0032】(比較例4)外径2.0mm軟鋼線上に造 彩剤の酸化ビスマス25重量%添加した熱可塑性ポリウ レタン樹脂を厚さ30±5μm押出し被覆した後、縮組 機により外間に綱組(素線径O.035mm、SUS3 04)を施し、これを加熱した金型ダイスを通して、編 網を内層に食い込ませた後、さらにその外周に熱可整性 ポリウレタン樹脂(造影剤無し)を押出し被覆し、外径 2. 2mmとした。これを2. 5mに切断し、金属線を 抜いてトルク伝達部を作製した。次に、外径2.0mm の軟銅線に熱可塑性ポリウレタン樹脂を押出し被覆し外 径2.2mmとした金属綱組のないものを作製し、金属 線を抜いた0.1mの先端チューブを作製した。これを 先のトルク伝達部の片末端に熱酷着により接続し、カテ ーテルチューブを得た。

【0033】そして、作製したカテーテルチュープ5本 抜いてトルク伝達部を作製した。次に、外径2.0mm 50 を撚回及び尾曲によりトルク伝達部の縄組層部での到離 を調べたところ、比較例1ほどではないが撚回や屈曲を 繰り返すと剥離が発生した。また、先端接続部の40R の屈曲50回において、欠落は生じなかったが、割れが 生じやすいものであった。さらに、線組を内層に食い込 ませたため、部分的にチューブ内に疑細が露出し、風曲 により、露出部に割れが生じた。

[0034]

【発明の効果】以上要するに本発明によれば、液状の禁 外織又は熱硬化樹脂組成物を用いるようにしたことか ら、従来のように接着層や内層に編組を埋め込ませない 10 【符号の説明】 でも綱組層で剥離が生じないものが容易に得られる。ま た、金属線と紫外線硬化樹脂及び型を用いて先韓チュー プとトルク伝達部とを接続するようにしたことから、強 固で内径変化や凸部の無い良好な接続が行われる。従っ て、トルク伝達部での剥離や縞組の露出、先端チューブ の脱落などの心配のない高品質の超纖径カテーテルチュ ープを安定して得ることができる等といった優れた効果 を発揮することができる。

[図面の簡単な説明]

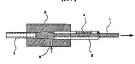
10 【図1】本発明の製造方法の一形態を示す説明図であ

【図2】(A)はカテーテルチューブの先端チューブの 一形態を示す横断面図である。(B) はカテーテルチュ 一プのトルク伝達部の一形態を示す横断所図である。 【図3】(A) はカテーテルチューブの先端チューブの 他の形態を示す機断面図である。(B) はカテーテルチ ューブのトルク伝達部の他の形態を示す横断面図であ **ک**ړ.

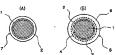
1 線状体

- 2 熱硬化シリコーン層
- 3 (3 a) 内層チューブ
- 1 編組
- 5 (5a) 外層チューブ
- 6 (6 a) トルク伝達部 7 (7 a) 先輩チューブ
- 8型
- 9 樹脂注入部

[2]1]



[図2]



[図3]

